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RPCC Pharmacy Forum

Special Interest Articles:

- Shingrix
- Sublocade
- Giapreza
- Secnidazole

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Did you know?

U.S Food and Drug Administration is advising caution be used in prescribing clarithromycin (Biaxin) to patients with heart disease. Clinical trial, CLARICOR, observed an unexpected increase in deaths among patients with coronary heart disease who were prescribed a two-week course of clarithromycin after patients were followed for one year or longer.

Laura Read RPh, CSPI
Laura.Read@childrensal.org
Patty Callahan PharmD, SPI
Patty.Callahan@childrensal.org
Regional Poison Control Center, Birmingham, AL

Shingrix- The Newest Herpes Zoster Vaccine

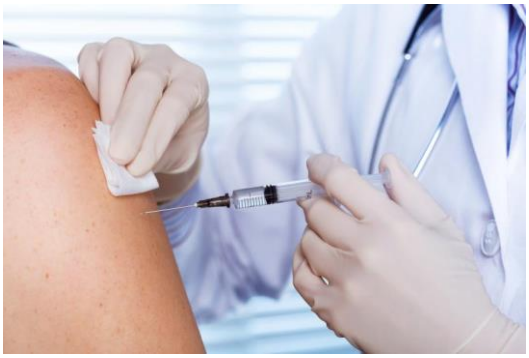
Angela O'Neil, Samford University PharmD Candidate, 2018

Shingrix, Zoster Vaccine Recombinant (RZV), was approved on October 20, 2017 by the Food and Drug Administration for the prevention of herpes zoster in adults aged 50 and older. Herpes Zoster, commonly referred to as shingles, is a localized, cutaneous eruption that is usually painful and is caused from the reactivation of latent varicella zoster virus (VZV). There are approximately one million cases per year occurring in the United States and the incidence increases with age, making it a common condition seen in the elderly population. The most common complication from the virus is postherpetic neuralgia, a persistent pain for at least 90 days following the resolution of the rash.

Shingrix is a two dose vaccine series that is given intramuscularly, with the second dose given two to six months after the first. Efficacy of RZV was evaluated in a two-part, phase three, multicenter clinical trial with over 30,000 people. Patients were randomized 1:1 to receive either Shingrix or placebo. Two groups, one for patients aged 50-69 and the other aged 70 or older, were prospectively followed for 3-4 years to determine the efficacy of RZV in the prevention of herpes zoster. In all ages studied, Shingrix was found to be greater than 90% effective at the prevention of herpes zoster. The most common adverse effect was injection site reactions. Shingrix vaccine should be stored in the refrigerator.

Zostavax, previously the only herpes zoster vaccine available, is a one dose, live attenuated strain of VZV, that is given subcutaneously. It is approved for the prevention of herpes zoster in immunocompetent adults aged 50 and older and the Advisory Committee on Immunization Practices (ACIP) recommends its use to start at 60 years old. Zostavax efficacy trials showed it to have 70% efficacy in preventing shingles in adults aged 50-59, but efficacy decreased markedly as a person aged. Zostavax vaccine should be stored in the freezer.

ACIP has recommended Shingrix to be used preferentially over Zostavax in adults aged 50 and older due to its greater efficacy at the prevention of herpes zoster. Patients who had previously received Zostavax are recommended to be revaccinated with Shingrix to increase their protection against the virus and can be given other needed vaccines at the same time due to Shingrix being a recombinant vaccine unlike Zostavax. No safety issues have been identified in patients who have received both Shingrix and Zostavax or in children who have been accidentally given Shingrix instead of the varicella vaccine. Shingrix is now widely available at many pharmacies and physician's offices.



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Sublocade™ as Once-Monthly Treatment for Opioid Use Disorder

Rachel Horne, Auburn University PharmD Candidate, 2018

The opioid epidemic in the United States has escalated since 1999, with an estimated 115 Americans currently dying every day from an opioid overdose. Sublocade is a new, once-monthly, injectable buprenorphine formulation, for treatment of moderate to severe opioid use disorder (OUD). Buprenorphine is a partial opioid agonist that is indicated for the treatment of moderate to severe OUD in patients who have already begun taking a trans-mucosal, buprenorphine-containing product for at least 7 days.

Sublocade is given via a subcutaneous injection in the abdomen, and should not be given IV, as it can cause very serious harm or even death. Sublocade forms a solid mass when it comes into contact with bodily fluids. Occlusion, tissue damage, and thrombo-embolic events, including pulmonary emboli, may occur if administered IV. Due to its dangerous potential, this medication is intended to be administered only by trained healthcare providers. Injections are provided in two formulations: 100mg/0.5 mL and 300 mg/1.5 ml. Dosing starts at 300 mg SQ in the abdomen for the first two months, followed by 100 mg per month, thereafter.

"Sublocade was statistically superior to the placebo group in regard to self-reporting and negative urine samples for illicit opioids"

Sublocade efficacy was proven in a phase three, 24-week, double - blind study with the following treatment arms: once-monthly 300 mg dose; two once-monthly 300 mg doses followed by four once-monthly 100 mg doses; or 6 once-monthly SQ injections of placebo. All patients were treated with buprenorphine/naloxone (Suboxone) sublingual film prior to enrollment in the study. A total of 504 patients were randomized into the study. Sublocade was statistically superior to the placebo group in regard to self-reporting and negative urine samples for illicit opioids.

Common side effects of Sublocade use include constipation, nausea, headache, injection site pruritus, vomiting, increased hepatic enzymes, fatigue, and injection site pain. Sublocade is available only as part of a Risk Evaluation and Mitigation Strategy (REMS) program due to its boxed warning for risk of serious harm or death with IV administration. Symptoms of Sublocade overdose include pinpoint pupils, sedation, hypotension, respiratory depression, and death. Treat overdoses by monitoring cardiac and respiratory status of the patient. Naloxone may be of some value in a buprenorphine overdose, although, higher than normal doses and repeated administration may be necessary.

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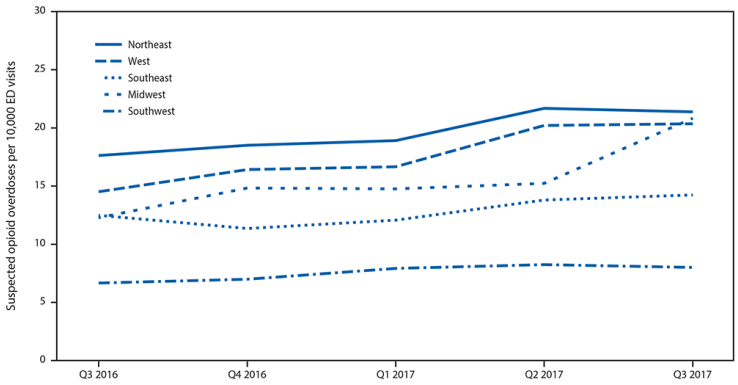

Quarterly rate* of suspected opioid overdose, by U.S. region, July 2016 – September 2017 (CDC)

Giapreza™ - Novel Vasoactive Agent

Luke Saunders, Samford University PharmD Candidate, 2018

Giapreza (synthetic human angiotensin II) is a new injectable, approved by the FDA in December 2017, for the treatment of severely low blood pressure associated with distributive or septic shock. Giapreza administration helps treat symptoms of shock by stimulating aldosterone release, causing direct vasoconstriction of vessel walls in septic patients. This is accomplished by stimulation of a G-couple protein receptor which results in smooth muscle contraction. This mechanism combats profound hypotension in septic patients due to the release of inflammatory cytokines in response to an infectious pathogen. Phase 3 trials concluded a statistically significant difference in MAP achievement in Giapreza versus placebo.

Dosing of Giapreza starts at 20 ng/kg/min IV, and many be increased by 15 ng/kg/min IV every 5 minutes up to a maximum of 80 ng/kg/min in the first 3 hours of treatment to achieve a MAP of 65. Maintenance dose is 40 ng/kg/min and may be decreased by 15 ng/kg/min IV every 5-15 minutes once shock symptoms have improved. Giapreza has an incredibly short half-life (less than 1 minute) allowing for the opportunity for rapid titration. Giapreza is metabolized to non-clinically significant metabolites. It does not require renal or hepatic adjustment and has not shown pharmacokinetic differences in the elderly or patients of differing sex.

Giapreza should be used with venous thromboembolism prophylaxis as there is some increased risk of thromboembolism (particularly deep vein thrombosis) associated with use of Giapreza vs. placebo. Other adverse reactions include: thrombocytopenia, tachycardia, fungal infection, delirium, acidosis, hyperglycemia and peripheral ischemia. Drug interactions may be seen more often with co-administration of angiotensin-converting enzyme inhibitors, which can increase the action of Giapreza. Co-administration of angiotensin receptor blockers may decrease the effectiveness of Giapreza. Giapreza is currently available for use.

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American Society for Prevention of Cruelty to Animals (ASPCA) Top Toxins

Regional Poison Control Center's primary focus is humans, however, it is interesting to see that through the ASPCA's hotline, Alabama's number one ingestion was etofenprox, an insecticide. Delaware is the only state in the country where the top toxin call is about grapes.

Secnidazole: The First Single-Dose Oral Treatment for Bacterial Vaginosis

Taylor Bailey, Samford University PharmD Candidate 2018

Bacterial vaginosis is the most common gynecologic infection in the United States, affecting 21 million women ages 14 to 49, annually. Solosec™ (secnidazole) is a recently FDA approved, single-dose, oral medication to treat bacterial vaginosis in adult women. It is a potent, next-generation, 5-nitroimidazole antibiotic with enhanced pharmacokinetic properties shown to be well tolerated and efficacious in therapy.

Solosec is the first oral antibiotic that has been brought to the market to treat bacterial vaginosis in more than a decade. Prior to the addition of Solosec, prescribed oral bacterial vaginosis treatment required twice-a-day dosing for seven days. This extended length of therapy has been shown to have only 50 percent adherence. When left untreated, bacterial vaginosis can increase the chance of contracting sexually transmitted diseases including gonorrhea, herpes, trichomaniasis, HIV and chlamydia. Recent studies have reported that 60 percent of recurrent sufferers reported a negative impact on work attendance, job performance and productivity. A single dose regimen has the potential to improve adherence in many patients.

A dose of secnidazole is supplied in the form of a 2 gram packet of granules. Patients can sprinkle the granules over pudding, yogurt or applesauce and are instructed to swallow the mixture within 30 minutes without crunching or chewing the granules. The FDA determined that secnidazole was safe and effective based on two randomized, placebo-controlled clinical trials involving over 300 women up to 54 years of age. In both trials, a higher percentage of patients taking Solosec qualified as clinical and therapeutic responders when compared to patients who received placebo. The most common side effects reported in the two studies were vulvovaginal candidiasis, nausea, vomiting, and headache. Solosec is not recommended for women who are breast-feeding.

The convenience and ease of administration associated with single-dose therapy along with its safe and tolerable profile make Solosec a seemingly fitting option in comparison to other single-dose treatments and a plausible alternative to other drugs in this class with multiple dosage regimens.

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